



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0634]

Cell-Based Products for Animal Use; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #218 (GFI #218) entitled "Cell-Based Products for Animal Use." FDA is aware that many potential veterinary therapies may be produced using cell-based products. GFI #218 describes FDA's Center for Veterinary Medicine's current thinking on cell-based products for animal use that meet the definition of a new animal drug. This guidance is for persons developing, manufacturing, or marketing cell-based products, including "animal stem cell-based products".

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lynne Boxer, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0611, lynne.boxer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 1, 2014 (79 FR 44803), FDA published the notice of availability for a draft guidance for industry #218 entitled "Cell-Based Products for Animal Use" giving interested persons until September 30, 2014, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 1, 2014.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Cell-Based Products for Animal Use. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 514 and 21 CFR 511.1 have been approved under OMB control numbers 0910-0032 and 0910-0117, respectively.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: June 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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